# EXHIBIT 6

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION**
**DECISION SUMMARY**
**ASSAY ONLY TEMPLATE**

## A. 510(k) Number:

k163101

## B. Purpose for Submission:

New device

## C. Measurand:

Buprenorphine

## D. Type of Test:

Qualitative and semi-quantitative immunoassay

## E. Applicant:

Microgenics Corporation

## F. Proprietary and Established Names:

CEDIA Buprenorphine II Assay
CEDIA Buprenorphine II Calibrators
CEDIA Negative Calibrator II
CEDIA Buprenorphine II Control Set

## G. Regulatory Information:

| Regulation section | Classification | Product Code | Panel |
|---|---|---|---|
| 21 CFR 862.3650 | Class II | DJG | Toxicology (91) |
| 21 CFR 862.3200 | Class II | DLJ | Toxicology (91) |
| 21 CFR 862.3280 | Class I, reserved | LAS | Toxicology (91) |

## H. Intended Use:

1. Intended use(s):

Refer to Indications for Use below

2. Indication(s) for use:

The CEDIA® Buprenorphine II Assay is a homogeneous enzyme immunoassay for the qualitative and/or semiquantitative determination for the presence of buprenorphine and its metabolites in human urine at a cut-off concentration of 10 ng/mL. The assay is intended to be used in laboratories and provides a simple and rapid analytical screening procedure to detect buprenorphine in human urine. The assay is designed for use with a number of clinical chemistry analyzers.

The semi-quantitative mode is for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as LC-MS/MS or permitting laboratories to establish quality control procedures.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) or Liquid chromatography/ mass spectrometry (LC-MS/MS) is the preferred confirmatory method.

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary results are used. For In Vitro Diagnostic Use Only.

CEDIA® Buprenorphine II Calibrators:
The CEDIA® Buprenorphine II calibrators and CEDIA Negative Calibrator II are intended for the calibration of the CEDIA® Buprenorphine II Assay in human urine. For In Vitro Diagnostic Use Only.

CEDIA® Buprenorphine II Control Set:
The CEDIA® Buprenorphine II controls are used to validate the CEDIA® Buprenorphine II Assay calibration in human urine. For In Vitro Diagnostic Use Only.

3. Special conditions for use statement(s):

For prescription use only.

4. Special instrument requirements:

The CEDIA Buprenorphine II Assay is intended for use on automated clinical analyzers capable of maintaining a constant temperature, pipetting, mixing reagents, measuring enzymatic rates at 570 nm and timing the reaction accurately can be used to perform this immunoassay. All performance data was collected on a Beckman Coulter AU680 analyzer.

## I. Device Description:

CEDIA® Buprenorphine II Assay is supplied as two liquid and two lyophilized reagent

kit homogeneous enzyme immunoassay:

1 EA Reconstitution Buffer
Contains buffer salts, mouse monoclonal anti-buprenorphine derivative antibody 0.8 - 1.0 mg/L, stabilizer, and preservative.

1a EA Reagent
Contains 0.171 g/L Enzyme Acceptor, buffer salts and preservative.

2 ED Reconstitution Buffer
Contains buffer salts, stabilizers, and preservatives

2a ED Reagent
Contains 0.175 mg/L Enzyme Donor conjugated to buprenorphine derivative, 1.67 g/L chlorophenol red-β-D-galactopyranoside, stabilizers, detergent and preservative.

The assay uses specific antibodies that can detect buprenorphine and its metabolites without significant cross-reactivity to other opiate compounds. In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzymes. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed, and resultant absorbance change, is directly proportional to the amount of analyte present in the sample.

## J. Substantial Equivalence Information:

1. Predicate device name(s):

   Microgenics CEDIA Buprenorphine Assay

2. Predicate 510(k) number(s):

   k040316

3. Comparison with predicate:

| **Similarities - Assay** | | |
|---|---|---|
| Item | Device | k040316 – Microgenics CEDIA Buprenorphine Assay |
| Intended Use | Same | Detection of buprenorphine in human urine |
| Methodology | Same | CEDIA (Cloned Enzyme |

| Similarities - Assay | | |
|---|---|---|
| Item | Device | k040316 – Microgenics CEDIA Buprenorphine Assay |
| | | Donor Immunoassay) |
| Intended Users | Same | Prescription users only |
| Reagents Form | Same | Lyophilized (requiring reconstitution) and liquid ready to use |
| Antibody | Same | Mouse monoclonal |
| Storage | Same | 2 – 8° C until expiration date |
| Target Analyte | Same | Buprenorphine |

| Differences - Assay | | |
|---|---|---|
| Item | Device | Predicate |
| Cutoff | 10 ng/mL | 5 ng/mL |

| Similarities – Calibrators | | |
|---|---|---|
| Item | Device | Predicate |
| Form | Same | Liquid – ready to use |
| Storage | Same | 2 – 8° C until expiration date |

| Differences - Calibrators | | |
|---|---|---|
| Item | Device | Predicate |
| Calibrator Name | CEDIA®<br>Buprenorphine II calibrators and controls | CEDIA®<br>Buprenorphine calibrators and controls |
| Calibrator Levels | 0, 10, 20, 50, 100 ng/mL | 0, 5, 20, 50, 75 ng/mL |

| Similarities – Controls | | |
|---|---|---|
| Item | Device | Predicate |
| Form | Same | Liquid – ready to use |
| Storage | Same | 2 – 8° C until expiration date |

| Differences - Controls | | |
|---|---|---|
| Item | Device | Predicate |
| Control Names | CEDIA® Buprenorphine II controls | CEDIA® Buprenorphine controls |
| Control Levels | 7.5 and 12.5 ng/mL | 3 and 7 ng/mL |
| Form | Same | Liquid – ready to use |
| Storage | Same | 2 – 8$^{o}$ C until expiration date |

**K. Standard/Guidance Document Referenced (if applicable):**

- CLSI EP05-A3 - Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline - Third Edition.
- CLSI EP06-A- Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline.
- CLSI EP07-A2 - Interference Testing In Clinical Chemistry; Approved Guideline - Second Edition.
- CLSI EP09-A3 - Measurement Procedure Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Third Edition.
- CLSI EP25-A- Evaluation of Stability of In Vitro Diagnostic Reagents; Approved Guideline.

**L. Test Principle:**

CEDIA® technology uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously re-associate to form fully active enzymes that, in the assay format, cleave a substrate. This generates a color change that can be measured spectrophotometrically.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

*a. Precision/Reproducibility:*

Precision was evaluated using CLSI Guideline EP05-A3 as a guideline, at one site with one analyzer, two operators, and two lots of reagents, calibrators and controls. Testing was carried out for 20 days with two runs per day, at least two hours apart and two replicates per run in both Qualitative and Semi-quantitative modes, giving a total of 80 determinants (n = 80). Drug-free negative urine was spiked with buprenorphine analyte to final concentrations of -100%, -75%,

-50%, -25%, below cutoff and +25%, +50%, +75% and +100%, above cutoff, and the concentrations were confirmed by LC-MS/MS. Results are summarized below:

Qualitative Mode – Lot 1

| % of Cutoff | Target Conc. (ng/mL) | Measured Conc. (ng/mL) | # of determinants | # Negative/ # Positive |
|---|---|---|---|---|
| -100 | 0 | 0 | 80 | 80/0 |
| -75 | 2.5 | 2.99 | 80 | 80/0 |
| -50 | 5 | 5.31 | 80 | 80/0 |
| -25 | 7.5 | 7.63 | 80 | 80/0 |
| 100 | 10 | 10.99 | 80 | 18/62 |
| +25 | 12.5 | 12.97 | 80 | 0/80 |
| +50 | 15 | 15.05 | 80 | 0/80 |
| +75 | 17.5 | 18.92 | 80 | 0/80 |
| +100 | 20 | 20.38 | 80 | 0/80 |

Qualitative Mode – Lot 2

| % of Cutoff | Target Conc. (ng/mL) | Measured Conc. (ng/mL) | # of determinants | # Negative/ # Positive |
|---|---|---|---|---|
| -100 | 0 | 0 | 80 | 80/0 |
| -75 | 2.5 | 2.99 | 80 | 80/0 |
| -50 | 5 | 5.31 | 80 | 80/0 |
| -25 | 7.5 | 7.63 | 80 | 80/0 |
| 100 | 10 | 10.99 | 80 | 27/53 |
| +25 | 12.5 | 12.97 | 80 | 0/80 |
| +50 | 15 | 15.05 | 80 | 0/80 |
| +75 | 17.5 | 18.92 | 80 | 0/80 |
| +100 | 20 | 20.38 | 80 | 0/80 |

Semi-Quantitative Mode – Lot 1

| % of Cutoff | Target Conc. (ng/mL) | Measured Conc. (ng/mL) | # of determinants | # Negative/ # Positive |
|---|---|---|---|---|
| -100 | 0 | 0 | 80 | 80/0 |
| -75 | 2.5 | 2.99 | 80 | 80/0 |
| -50 | 5 | 5.31 | 80 | 80/0 |
| -25 | 7.5 | 7.63 | 80 | 80/0 |
| 100 | 10 | 10.99 | 80 | 7/73 |
| +25 | 12.5 | 12.97 | 80 | 0/80 |
| +50 | 15 | 15.05 | 80 | 0/80 |
| +75 | 17.5 | 18.92 | 80 | 0/80 |
| +100 | 20 | 20.38 | 80 | 0/80 |

Semi-Quantitative Mode – Lot 2

| % of Cutoff | Target Conc. (ng/mL) | Measured Conc. (ng/mL) | # of determinants | # Negative/ # Positive |
|---|---|---|---|---|
| -100 | 0 | 0 | 80 | 80/0 |
| -75 | 2.5 | 2.99 | 80 | 80/0 |
| -50 | 5 | 5.31 | 80 | 80/0 |
| -25 | 7.5 | 7.63 | 80 | 80/0 |
| 100 | 10 | 10.99 | 80 | 35/45 |
| +25 | 12.5 | 12.97 | 80 | 0/80 |
| +50 | 15 | 15.05 | 80 | 0/80 |
| +75 | 17.5 | 18.92 | 80 | 0/80 |
| +100 | 20 | 20.38 | 80 | 0/80 |

b. *Linearity/assay reportable range:*

The sponsor performed a spike recovery study using two lots each of reagent, calibrators and controls and analyzed concentrations of 7.5, 10, and 12.5 ng/mL. Samples were analyzed in semi-quantitative mode in replicates of 5. Recoveries ranged from 96.6% - 105.3%.

The sponsor also performed a linearity study using two lots each of reagent, calibrators and controls and analyzed concentrations of 0, 5, 10, 20, 30, 40, 50, 60, 70, 80, 90, and 100 ng/mL. Samples were analyzed in semi-quantitative mode in replicates of 5. Recoveries ranged from a low of 98.3% to a high of 119.8%. Recovery at the claimed cutoff of 10 ng/mL was 109.7%.

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

Traceability: The primary calibrators and controls are treaceable to a commercially available Buprenorphine drug stock with a starting concentration of 1 mg/mL.

Value Assignment: The nominal values for calibrators are 0, 10, 20, 50 and 100 ng/mL, and 7.5 and 12.5 ng/mL for controls. All values are verified by LC-MS/MS.

The sponsor's protocols and acceptance criteria were reviewed and found to be acceptable.

Stability: Real time and accelerated stability studies for both controls and calibrators were conducted. Protocols and acceptance criteria were reviewed and found to be acceptable. The results support the manufacturer's stability claims of 60 days for an opened vial and 18 months for an unopened vial for both calibrators and controls. Real time studies are ongoing.

*d. Detection limit:*

Not applicable.

*e. Analytical specificity:*

Buprenorphine and metabolites

To evaluate cross-reactivity, drug-free urine was spiked with norbuprenorphine, buprenorphine-β-D-glucuronide and norbuprenorphine-β-D glucuronide. Percent cross-reactivity was calculated as (Cut-off concentration / Lowest concentration of cross reactant that gives a positive result) x 100. Results are summarized below:

| Compound | Lowest concentration producing a positive result (ng/mL) | Percent cross-reactivity |
|---|---|---|
| Buprenorphine | 10 | 100 |
| Norbuprenorphine | 8 | 125 |
| Buprenorphine-β-D-glucuronide | 13 | 77 |
| Norbuprenorphine-β-D-glucuronide | 10 | 100 |

Opiates and Structurally Related Compounds

The following opiates and structurally related compounds were analyzed and found to have a cross-reactivity of <0.01%.

| Compound | Highest Concentration Tested | Result |
|---|---|---|
| 6-Acetyl morphine | 100,000 | Negative |
| Diacetylmorphine (Heroin) | 100,000 | Negative |
| Codeine | 100,000 | Negative |
| Dextromethorphan | 100,000 | Negative |
| Dihydrocodeine | 100,000 | Negative |
| EDDP (2-ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine) | 100,000 | Negative |
| EMDP ((2-Ethyl-5-methyl-3,3- | 100,000 | Negative |

| Compound | Highest Concentration Tested | Result |
|---|---|---|
| diphenylpyrroline) | | |
| Fentanyl | 100,000 | Negative |
| Hydrocodone | 100,000 | Negative |
| Hydromorphone | 100,000 | Negative |

The following opiates and structurally related compounds were analyzed and found to have a cross-reactivity of <0.1%.

| Compound | Highest Concentration Tested | Result |
|---|---|---|
| Hydromorphone-β-Dglucuronide | 10,000 | Negative |
| Oxymorphone-β-Dglucuronide | 10,000 | Negative |

Structurally unrelated compounds

Interference from structurally unrelated compounds was evaluated by spiking these compounds into urine samples containing near cutoff negative (7.5 ng/mL) and near cutoff positive (12.5 ng/mL) concentrations of buprenorphine. The compounds listed in the table below did not cause any positive or negative interference at the concentrations shown:

| Compound | Concentration tested |
|---|---|
| Acetaminophen | 500,000 |
| Acetylsalicylic acid | 500,000 |
| Amitryptyline | 50,000 |
| Amoxicillin | 100,000 |
| Amphetamine | 1,000,000 |
| Amisulpride | 100,000 |
| Benzoylecgonine | 1,000,000 |
| Caffeine | 100,000 |
| Carbamazepine | 100,000 |
| Chlorpromazine | 100,000 |
| Clomipramine | 25,000 |
| Chloroquine | 100,000 |
| Cimetidine | 500,000 |
| Desipramine | 10,000 |
| Doxepine | 25,000 |
| Diphenylhydramine | 100,000 |
| Ephedrine | 100,000 |

| Compound | Concentration tested |
|---|---|
| Fluoxethine | 100,000 |
| Fluphenazine | 100,000 |
| Hydroxychlroquine | 100,000 |
| Ibuprofen | 100,000 |
| Imipramine | 25,000 |
| Maprotiline | 100,000 |
| Mitragynine | 100,000 |
| 7-OH Mitragynine | 10,000 |
| Nalbuphine | 100,000 |
| Nortryptiline | 50,000 |
| Oxazepam | 100,000 |
| Phencyclidine | 100,000 |
| Phenobarbital | 100,000 |
| Ranitidine | 500,000 |
| Secobarbital | 100,000 |
| Sulpiride | 100,000 |
| Thioridazine | 100,000 |
| Trimipramine | 25,000 |

Endogenous compounds

Potential interference from endogenous compounds was evaluated by spiking these compounds into urine samples containing near cutoff negative (7.5 ng/mL) and near cutoff positive (12.5 ng/mL) concentrations of buprenorphine. The compounds or conditions listed in the table below did not cause any positive or negative interference at the concentrations shown:

| Compounds | Tested Conc. (mg/dL) |
|---|---|
| Negative Urine | 0 |
| Acetaminophen | 10 |
| Acetone | 500 |
| Acetylsalicylic Acid | 10 |
| Ascorbic Acid | 150 |
| Caffeine | 10 |
| Creatinine | 400 |
| Ethanol | 10 |
| Galactose | 5 |
| Glucose | 1000 |
| Hemoglobin | 150 |
| Human Serum Albumin | 200 |
| Ibuprophen | 10 |
| Oxalic acid | 50 |

| Compounds | Tested Conc. (mg/dL) |
|---|---|
| Riboflavin | 3 |
| Sodium Chloride | 1000 |
| Urea | 1000 |

Specific gravity and pH

Interference from specific gravity and pH was evaluated by adjusting the specific gravity and pH of samples with near cutoff negative (7.5 ng/mL) and near cutoff positive (12.5 ng/mL) concentrations of buprenorphine. The following specific gravity or pH levels did not cause any positive or negative interference:

Specific gravity of 1.002, 1.004, 1.008, 1.013, 1.016, 1.018, 1.022, 1.023, 1.025, and 1.030.

pH of 3, 4, 5, 6, 7, 8, 9, 10, and 11

*f. Assay cut-off:*

Analytical performance of the device around the claimed cutoff is described in precision section (1 a.) above.

2. Comparison studies:

*a. Method comparison with predicate device:*

Candidate Device Results vs. stratified LC-MS/MS Values – Semi-quantitative

| Candidate Device Results | **Negative** or less than half the cutoff concentration by LC-MS/MS analysis | **Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS analysis) | **Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS analysis) | **High Positive** (greater than 50% above the cutoff concentration by LC-MS/MS analysis) |
|---|---|---|---|---|
| Positive | 43 | 4 | 5 | 45 |
| Negative | 50 | 6 | 0 | 0 |

LC-MS/MS values used to categorize samples in this table are based on the concentration of buprenorphine found in the sample.

% Agreement among positives is 50/50 = 100%
% Agreement among negatives is 56/103 = 54%

Candidate Device Results vs. stratified LC-MS/MS Values – Qualitative

| Candidate Device Results | **Negative** or less than half the cutoff concentration by LC-MS/MS analysis | **Near Cutoff Negative** (Between 50% below the cutoff and the cutoff concentration by LC-MS/MS analysis) | **Near Cutoff Positive** (Between the cutoff and 50% above the cutoff concentration by LC-MS/MS analysis) | **High Positive** (greater than 50% above the cutoff concentration by LC-MS/MS analysis) |
|---|---|---|---|---|
| Positive | 42 | 4 | 5 | 45 |
| Negative | 51 | 6 | 0 | 0 |

LC-MS/MS values used to categorize samples in this table are based on the concentration of buprenorphine found in the sample.

% Agreement among positives is 50/50 = 100%
% Agreement among negatives is 57/103 = 55%

Summary of discordant results

| Sample ID | Qual | Semi-Quant (ng/mL) | Bup | NorBup | BupGlu | NorBup Gluc |
|---|---|---|---|---|---|---|
| 51 | Pos | 10.08 | <0.65* | 2.27 | 1.96 | 6.18 |
| 52 | Pos | 10.02 | <0.65* | 0.69 | 3.15 | 6.84 |
| 53 | Neg | 10.42 | <0.65* | 1.08 | 7.89 | 1.82 |
| 54 | Pos | 11.59 | <0.65* | 1.09 | 5.67 | 5.54 |
| 55 | Pos | 10.40 | <0.65* | 3.27 | 2.54 | 7.92 |
| 56 | Pos | 16.36 | <0.65* | 4.02 | 7.46 | 3.73 |
| 57 | Pos | 17.31 | <0.65* | 3.28 | 10.67 | 3.09 |
| 58 | Pos | 19.82 | <0.65* | 5.03 | 10.91 | 2.05 |
| 59 | Pos | 18.73 | <0.65* | 3.10 | 9.09 | 6.59 |
| 60 | Pos | 22.63 | <0.65* | 4.18 | 8.30 | 7.34 |
| 61 | Pos | 18.95 | <0.65* | 1.96 | 9.90 | 9.90 |
| 62 | Pos | 26.11 | <0.65* | 4.36 | 10.87 | 6.92 |
| 63 | Pos | 24.99 | <0.65* | 5.26 | 8.41 | 9.01 |
| 64 | Pos | 24.91 | <0.65* | 3.86 | 23.19 | <0.65* |
| 65 | Pos | 20.87 | <0.65* | 1.44 | 14.06 | 14.06 |
| 66 | Pos | 23.21 | <0.65* | 2.23 | 25.24 | 2.50 |
| 67 | Pos | 30.27 | <0.65* | 4.42 | 8.82 | 16.84 |
| 68 | Pos | 31.35 | <0.65* | 16.52 | 9.41 | 5.47 |

| Sample ID | Qual | Semi-Quant (ng/mL) | Bup | NorBup | BupGlu | NorBup Gluc |
|---|---|---|---|---|---|---|
| 69 | Pos | 35.38 | <0.65* | 7.13 | 5.30 | 22.38 |
| 70 | Pos | 40.38 | <0.65* | 12.21 | 18.65 | 9.11 |
| 71 | Pos | 38.44 | <0.65* | 2.93 | 12.40 | 28.84 |
| 72 | Pos | 48.60 | <0.65* | 23.41 | 15.34 | 5.44 |
| 73 | Pos | 62.31 | <0.65* | 5.47 | 36.52 | 25.00 |
| 74 | Pos | 81.31 | <0.65* | 33.59 | 23.42 | 12.72 |
| 75 | Pos | 88.67 | <0.65* | 26.22 | 32.43 | 23.1 |
| 76 | Pos | 79.26 | <0.65* | 6.34 | 80.00 | 2.77 |
| 77 | Pos | >100 | <0.65* | 8.63 | 56.89 | 46.95 |
| 78 | Pos | >100 | <0.65* | 101.98 | 10.40 | 9.90 |
| 79 | Pos | >100 | <0.65* | 7.91 | 26.43 | 144.00 |
| 80 | Pos | >100 | <0.65* | 49.66 | 97.61 | 121.12 |
| 81 | Pos | >100 | <0.65* | <0.65* | 145.72 | 394.81 |
| 82 | Pos | >100 | <0.65* | 129.95 | 105.07 | 664.47 |
| 83 | Pos | >100 | 0.81 | 32.14 | 39.52 | 59.14 |
| 84 | Pos | 63.54 | 0.86 | 7.41 | 29.46 | 31.38 |
| 85 | Pos | 20.48 | 0.90 | 5.42 | 11.54 | <0.65* |
| 86 | Pos | >100 | 0.91 | 54.00 | 18.10 | 10.52 |
| 87 | Pos | 46.32 | 2.00 | 12.03 | 13.58 | 16.24 |
| 88 | Pos | >100 | 2.00 | 6.83 | 193.42 | 131.65 |
| 89 | Pos | >100 | 2.02 | 75.75 | 174.74 | 442.98 |
| 90 | Pos | 66.32 | 2.48 | 6.53 | 57.67 | 1.52 |
| 91 | Pos | >100 | 3.63 | 80.26 | 733.7 | 624.02 |
| 92 | Pos | >100 | 4.38 | 69.28 | 146.16 | 349.33 |
| 93 | Pos | >100 | 4.45 | 59.03 | 55.01 | 17.31 |
| 100 | Pos | >100 | 8.64 | 36.91 | >1000** | 224.42 |
| 101 | Pos | >100 | 8.94 | 51.32 | 497.32 | 55.06 |
| 102 | Pos | >100 | 5.22 | 35.13 | 85.99 | 22.24 |
| 103 | Pos | 77.36 | 6.60 | 147.58 | 195.67 | 40.28 |

Abbreviations: Bup – Buprenorphine, NorBup – Norbuprenorphine, BupGlu – Buprenorphine Glucuronide, NorBupGluc – Norbuprenorphine Glucuronide

*0.65 ng/mL is the lower limit of quantitation for the buprenorphine, norbuprenorphine, buprenorphine-glucuronide and norbuprenorphine-glucuronide LC-MS/MS assays

**1000 ng/mL is the upper limit of quantitation for the buprenorphine, norbuprenorphine, buprenorphine-glucuronide and norbuprenorphine-glucuronide LC-MS/MS assays.

*b. Matrix comparison:*

Not applicable. This assay is intended to be used with urine samples only.

3. Clinical studies:

*a. Clinical Sensitivity:*

Not applicable.

*b. Clinical specificity:*

Not applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Not applicable.

**N. Proposed Labeling:**

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

**O. Conclusion:**

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.